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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,107	05/03/2001	Egon Persson	6176.200-US	7628

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EXAMINER	
SNEDDEN, SHERIDAN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,107	PERSSON ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/19/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,8,10-13,24,25,27 and 28* is/are rejected.

7)☒ Claim(s) *3-6,9 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 19 December 2003. Claims 14-23 and 29 have been canceled. Claims 1-13 and 24-28 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2, 7, 8, 10-13, 24-25, 27-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 and 7 of copending Application No. 10/109,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because scope of the claims are directed to identical subject matter. For instance, claims 1 and 7 of Application No. 10/109,498 recites a variant Factor VII peptide with at least one amino acid substitution. Claim 5 and 6 teach the substitution of Leu 305 with a Valine residue. Claims 1, 5, and 6 specifies the substitution of Leu 305 with either Val, Ile, or Tyr, where the variant exhibits increased bioactivity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicant may overcome this rejection by amending or canceling the conflicting claims in the current application or copending Application No. 10/109,498.

Applicant argues that a terminal disclaimer was filed with the response. However, the terminal disclaimer for 10/109,498 was not found in the file. Only, the terminal disclaimer regarding application 10/255,032 was present.

Maintained Objections and Rejections

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-2, 7, 8, 24-25, 27-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 and 7 of copending Application No. 10/281,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because scope of the claims are directed to identical

subject matter. For instance, claims 1, 5 and 8 of Application No. 10/281,727 recites a variant Factor VII peptide with the substitution of Leu 305 with any amino acid residue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicant may overcome this rejection by amending or canceling the conflicting claims in the current application or copending Application No. 10/281,727.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 7, 24, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Pedersen *et al.* (US 2003/0096338 A1). Pedersen *et al.* teach the a Factor VII polypeptide where L305 is substituted with Asn (see section [0126] and claim 44). These compounds would inherently possess the increased activity. The compounds are used in the treatment of bleeding episodes that would enhance homeostasis (see section [0011]). Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 7, 8, 24-25, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (Proc. Natl. Acad. Sci. USA 93, 14379-14384, 1996), and further in view of the Pedersen *et al.* (US 2003/0096338 A1), the Dictionary of Biochemistry and Molecular Biology (John Wiley & Sons, 2d ed. 1989), and Berkner *et al.* (US 5288629 A).

Dickinson *et al.* relates to Factor VII polypeptides wherein L305 has been replaced by Ala. Dickinson *et al.* teach that the substitution in the loss of proteolytic function. Dickinson *et al.* does not teach the above substitutions with any other amino acid other than Alanine. Dickinson *et al.* does not teach use of the peptides for the treatment of bleeding episodes.

Pedersen *et al.* teach the a Factor VII polypeptide where L305 is substituted with Asn (see section [0126] and claim 44). The compounds are used in the treatment of bleeding episodes that would enhance homeostasis (see section [0011]).

In the area of biotechnology, peptide may differ by a conservative substitutions defined as "the replacement in a protein of one amino acid by another, chemically similar, amino acid... [which] is generally expected to lead to either no change or only a small change in the properties of the protein." Dictionary of Biochemistry and Molecular Biology 97 (John Wiley & Sons, 2d ed. 1989).

Berkner *et al.* teach the use of a modified Factor VII molecule with reduces proteolytic function in a method treating bleeding episodes and or to enhance homeostasis. Berkner *et al.* teach that the reduced proteolytic function may be accompanied by fewer undesirable side effects than experienced with current therapies, as it would not lead to the degradation of other clotting factors.

Thus, it would have been it would have been obvious to the person of ordinary skill in the art at the time the invention was make conservative substitutions at L305 of Factor VII with amino acids conservative to Asn and Ala. Dickinson *et al.* teach that the substitutions at L305 result in the loss of proteolytic function, which as suggested by Berkner *et al.* is the desired activity required for treating bleeding episodes. Thus, it can at least be expected that similar substitution at the given positions would result in like activity. A person of ordinary skill in the art would have been motivated to make the above substitutions in order to create a variant with reduced proteolytic function that would act to interrupt the clotting cascade. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim Objections

10. Claims 3-6, 9, 26 are objected to because of the following informalities: the claims are dependent are rejected claims. Appropriate correction is required.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
April 30, 2004

SKS

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600